

# ASX/NASDAQ Media release

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# PHARMAXIS' ARIDOL GAINS SWEDISH APPROVAL

# AUSTRALIAN-MADE THERAPEUTIC PRODUCT GOES GLOBAL

Pharmaceutical company Pharmaxis (ASX:PXS, NASDAQ:PXSL) today announced that it has received marketing approval for its asthma diagnostic and management product Aridol in Sweden, a crucial market for gaining wider European approval.

Following the Swedish registration, Pharmaxis will seek marketing of Aridol in the 27 other European Union member states via the mutual recognition procedure. Individual approvals are expected from early next year.

Aridol is Australia's first true molecule-to-market therapeutic product – discovered, developed, manufactured and marketed over 12 years by wholly Australian interests. The exhaustive clinical trials were generously assisted by Australian Government research grants, including the current P3 Scheme.

A simple-to-use airways inflammation test, Aridol is administered as a dry powder in a hand-held inhaler. It is approved in Sweden to identify patients with asthma, determine the severity of their disease and the effectiveness of their current treatment.

Pharmaxis CEO Dr Alan Robertson said the Swedish approval opens the door for Aridol to reach asthma patients worldwide.

"The Swedish registration marks an exciting and historic milestone for Pharmaxis, extending our footprint into the important European market."

"It is equally thrilling to be bringing a truly Australian-made pharmaceutical discovery to the world – and the first indirect bronchial provocation test registered in Europe. Over coming years, we are optimistic Aridol will become established as the yardstick by which asthma is assessed globally."

Asthma affects 52 million people worldwide, many of whom may be receiving inappropriate medication because of the absence of an objective test - until now. Asthma cost the US healthcare system alone US\$15 billion in 2004. In 2003, asthma claimed 400 Australian and 4,500 US lives. Use of Aridol can improve patients' wellbeing and reduce the cost of asthma to healthcare systems.

Clinical trial results suggest that 25% of asthmatic patients are being treated with incorrect dosages of asthma medication, and up to 17% could reduce their medication without adverse effects.

Aridol's global revenue potential is projected at \$250 million a year. Distribution partners have been established for Scandinavia, Italy, Greece, Switzerland and other countries in anticipation of the EU approval. Following approval from the relevant authorities, Pharmaxis will work closely with distributors over the coming year to achieve a successful uptake of Aridol in the important European market.

To find out more about Pharmaxis, go to http://www.pharmaxis.com.au.

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### **About Aridol**

Asthma is among the top 10 most commonly cited reasons for consulting a General Practitioner (GP). Yet GPs currently rely upon older tests that are often inaccurate and cumbersome to assess airway inflammation in patients with asthma. The simple 15 minute test uses a patented formulation of mannitol processed into a respirable powder. The test requires the patient to inhale increasing doses of Aridol, which causes the airways to narrow and contract that is simply detected by measuring the amount of air a person can exhale in one second. The smaller the dose required to cause contraction, the more severe the patient's asthma diagnosis. People without airway inflammation do not respond to an Aridol challenge test. Doctors can use the results of this test to measure asthma severity and help guide treatment.

### About Pharmaxis

Pharmaxis (ACN 082 811 630) is a specialist pharmaceutical company involved in the research, development and commercialization of therapeutic products for chronic respiratory and autoimmune diseases. Its development pipeline of products include Aridol<sup>TM</sup> for the management of asthma, Bronchitol<sup>TM</sup> for cystic fibrosis and chronic obstructive pulmonary disease (COPD) and PXS64 for the treatment of multiple sclerosis.

Founded in 1998, Pharmaxis was listed on the Australian Stock Exchange in November 2003 (symbol PXS), and on NASDAQ (symbol PXSL) in August 2005. The company is headquartered in Sydney at its TGA-approved manufacturing facilities. For more information about Pharmaxis, go to www.pharmaxis.com.au or contact Jane Sugden, Investor Relations +61 2 9454 7230.

### Forward-Looking Statements

The statements contained in this press release that are not purely historical are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements in this press release include statements regarding our expectations, beliefs, hopes, goals, intentions, initiatives or strategies, including statements regarding the potential for Aridol and/or Bronchitol. All forward-looking statements included in this press release are based upon information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement as a result of new information, future events or otherwise. We can not guarantee that any product candidate will receive FDA or other regulatory approval or that we will seek any such approval. Factors that could cause or contribute to such differences include, but are not limited to, factors discussed in the "Risk Factors and Other Uncertainties" section of our Form 20-F lodged with the U.S. Securities and Exchange Commission.